

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

ADAM KANUSZEWSKI and
ASHLEY KANUSZEWSKI, as parent-
guardians and next friend to their minor
children, D.W.L., R.F.K., and C.K.K.;

SHANNON LAPORTE, as
parent-guardian and next friend to her
minor children, M.T.L. and E.M.O.;

and

LYNNETTE WIEGAND, as parent-
guardian and next friend to her minor
children, L.R.W., C.J.W., H.J.W., and
M.L.W.

Plaintiffs

v.

ELIZABETH HERTEL,
sued in her official capacity;

DR. SANDIP SHAH,
sued in his official capacity;

DR. SARAH LYON-CALLO,
sued in her official capacity;

MARY KLEYN,
sued in her official capacity; and

DR. ANTONIO YANCEY,
sued in his official capacity

Defendants

Case No.: 18-cv-10472

Hon. Thomas L. Ludington,
District Court Judge

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**RESPONSE IN OPPOSITION TO
DR. YANCEY'S MOTION FOR SUMMARY JUDGMENT**

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COUNTER STATEMENT OF QUESTION(S) PRESENTED

Should summary judgment be granted to Dr. Yancey?

Answer: No

MOST RELEVANT AUTHORITY

FRCP 56

Kanuszewski v. MDHHS, 927 F.3d 396 (6th Cir. 2019)

INTRODUCTION

Plaintiffs have already filed for summary judgment against Dr. Yancey. **ECF No. 135**. He has also responded (**ECF No. 145**) and Plaintiffs filed a reply (**ECF No. 153**). He also filed this motion for summary judgment (**ECF No. 149**) which mirrors the same. There is no dispute that Dr. Yancey is director of the Michigan Neonatal Biobank, Inc. He does not dispute that he has possessional control over each Plaintiff-Infant's blood spots, but has not obtained any consent to assume the same. For various reasons his counsel outlined, he suggests he is not responsible; this is despite being the last state actor in a chain of government officials and is the one today who holds the blood spots for unauthorized use by third parties in the face of lacking informed parental consent. No permission was sufficiently secured for the Biobank to receive, be transferred, have, hold, distribute, and use the blood spots of these infants born from 2008 through 2017—yet he, from his perspective sued in his official capacity, has no Section 1983 liability or responsibility. His arguments fail. Summary judgment should be denied.

COUNTER-FACTS

Plaintiffs incorporate by reference the facts, arguments, and supporting evidence in their Motion for Summary Judgment. **ECF No 135**. A brief summary follows.

The Michigan Neonatal Biobank operates under the directorship¹ of Defendant Dr. Antonio Yancey. **Yancey Dep., ECF No. 135-40, PageID.2386 (p. 5)**. He is involved after the newborn screenings are fully completed. As he succinctly explains it—

so what happens is that any residual blood spots that are left from testing at the State lab, those are basically sent to the Biobank, to the operations that I manage, and then our job is to get those blood spots and we basically store them in our storage facility.

Id. at PageID.2388 (p. 12). At the Biobank, the blood spots are stored until such time as they can be sold to researchers as part of for-profit or public-based science research projects. **Id. at PageID.2389 (p. 17)**.² Dr. Yancey claims everything is accomplished through and by the State Defendants. **Id. at PageID.2390 (p. 21)**. However, the fatal flaw in Dr. Yancey's legal presentation is the lack of any proof of consent from the parents (let alone sufficient consent) to have any blood samples transferred from the State Defendants (at the completion of the screening process) to the Biobank he operates and oversees. **Kanuszewski Dec., ECF No. 135-25; LaPorte Dec., ECF No. 135-26; Weigand Dec., ECF No. 135-27**.³ Even worse,

¹ In his motion papers, Dr. Yancey asserts he is the "executive director" of the Biobank. **ECF No. 149-1, PageID.4866**. It is unclear if this true because he testified in his deposition that was the "director." **Yancey Dep., ECF No. 135-40, PageID.2386**. This seemingly is a distinction without a difference.

² See also <https://mnb.wayne.edu/research> (copy attached as **Exhibit A**)

³ The Court should take particular note of paragraph 5 of each declaration.

consent is never obtained by the Biobank, ever. **Yancey Dep., ECF No. 135-40, PageID.2395-2396 (pp. 40, 42-45)**. Dr. Yancey never acknowledges this fatal shortcoming in his briefing. Already, the Sixth Circuit has found that the “Neonatal Biobank is an arm of the state.” *Kanuszewski v. MDHHS*, 927 F.3d 396, 418 fn.8 (6th Cir. 2019). And Dr. Yancey already conceded at deposition he is working in “joint concert with [the State Defendants] to put material [blood spots] into the storage facility for long-term storage” for later uses. *Id.* **at 23, 33**. Whether he realizes it or not, he is a state actor⁴ who is part of the process involving the retention, transfer, and storage of infant blood samples without sufficient parental consent and has violated the Constitution.

Dr. Yancey also goes to great lengths to trumpet how the newborn screening testing program is “one of the most valuable health tools developed over the past fifty years.” **ECF No. 149-1, PageID.4863**. And perhaps the testing part is.⁵ However, this case is focused on the actions

⁴ It is Plaintiffs’ position that Dr. Yancey is already a state actor sufficient under 42 U.S.C. § 1983 when being a vice president at Wayne State University as the directorship ties to his position at the university. **Yancey Dep., ECF No. 135-40, PageID.2386 (pp. 6-7)**. However, to the extent he is treated as a private party, private persons, jointly engaged with state officials in the prohibited action, are acting ‘under color’ of law for purposes of § 1983. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 152 (1970). “[T]o act ‘under color of’ state law for § 1983 purposes, it is enough that [the defendant] is a willful participant in joint action with the State or its agents. Private persons, jointly engaged with state officials in the challenged action, are acting ‘under color’ of law for purposes of § 1983 actions.” *Dennis v. Sparks*, 449 U.S. 24, 27-28 (1980).

⁵ And if it truly is (as formulated), then obtaining informed parental consent should be easy and straightforward. However, there is actually serious concerns about whether this program—from start to finish—is actually “one of the most valuable health tools” when

and activities of what happens after the newborn screening tests are completed. Dr. Yancey has misfocused on the early screening portion of the scheme when only the latter “subsequent retention, transfer, and storage of the samples” is subject to challenge before this Court.

A perfect example of this misunderstanding is on PageID.4868 wherein Dr. Yancey asserts “the Michigan process is overseen by a committee of ten (10) individuals” from various professional medical backgrounds. Yet, this “Committee” actually only “review[s] the list of newborn screening tests required” and “submit a written report to the department regarding the appropriateness of the existing list of required newborn screening tests.” MCL 333.5430(2). It has no part of or control over the post-screening activities of Defendants, i.e. the “subsequent retention, transfer, and storage of the samples” to the Biobank. See MCL 333.5430. So to say that the entire “Michigan process” is “overseen”—in the overbroad sense—by this ‘gang of ten’ is simply not a true and an inaccurate statement as the issues in dispute in the current case. See *infra*, Footnote 9.

This case is about consent and consent is about control—who has it and who can grant it. But consent can be only obtained from the grantor

balanced against medical privacy and personal autonomy. See **Kanuszewski Dec., ECF No. 135-25; LaPorte Dec., ECF No. 135-26; Weigand Dec., ECF No. 135-27.**

when the grantor is properly informed. These parents were never informed about Dr. Yancey, the Biobank, or what was happening therein—

Q. Do you feel that you were adequately informed about the nature and the scope of the newborn screening program, including indefinite retention of that sample at the Michigan Neonatal Biobank, at the time or shortly after your children were born?

A. No

ECF No. 145-5, PageID.4025 (Ashley Kanuszewski); see also **ECF No. 145-18, PageID.4103-4106** (LaPorte); **ECF No. 145-19, PageID.4123-4126** (Wiegand). That is fatal for Dr. Yancey. His indifference to the infants' medical privacy and their personal autonomy rights is not a good enough excuse; the Constitution demands better.

COUNTER ARGUMENT

Section 1983, 42 U.S.C. § 1983, creates a private right of action against state officials and private joint-concert actors who deprive individuals of constitutional rights under color of state law. *Barker v. Goodrich*, 649 F.3d 428, 432 (6th Cir. 2011); *Dennis v. Sparks*, 449 U.S. 24, 27-28 (1980).

I. Dr. Yancey has legal responsibilities under the Constitution.

A major theme throughout Dr. Yancey's briefing is to cast fault upon the State Defendants for his and his entity's nonconsensual retention of each infants' blood spots. As he presents it, "[t]he only thing the Biobank and Dr. Yancey do is store the blood." **ECF No. 149-1, PageID.4872**. This excuse

does not work. It is like the excuse used by the caught get-away driver claiming no legal guilt because the real wrong was undertaken by the rest of his gang who actually committed the robbery. Dr. Yancey's argument of unintelligent denial of responsibility is meritless.

A. *Spiering* does not help Dr. Yancey.

Dr. Yancey also argues that the challenge in this case as to post-screening retention, transfer, and storage of the samples is similar to or controlled by *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006). It really is not. Again, as noted above, Dr. Yancey focuses on the wrong issue being presented to this Court.

In *Spiering*, the challenge was the newborn testing itself—"parents [who] want to delay the state-mandated testing of their newly born infants for metabolic diseases because of their sincere religious beliefs..." *Id.* at 1130. Here, the instant challenge (by the Sixth Circuit's narrowing) is as to post newborn testing—an issue not addressed in *Spiering*. While *Spiering* may be of non-binding service to resolving whether Michigan's screening and testing pass constitutional muster, that portion of the case has not been permitted to be challenged in this Court here due to immunity and standing. *Spiering* is irrelevant to Dr. Yancey.

II. Dr. Yancey's other arguments fail.

A. The exhaustion argument is already precluded by the Sixth Circuit.

By an attempted second bitter bite at the apple, Dr. Yancey argues, once again, that because the parents can use a made-up, non-statutory state administrative process to cause the destruction of the samples that this civil rights case against him is precluded. See **ECF No. 149-1, PageID.4891-4892**.⁶ In addition to being a legally insufficient process, the Sixth Circuit already rejected that argument—

Defendants also argue that this is not a cognizable harm because a parent or guardian may request that a blood sample not be used for research “by contacting [the Department of Community Health] by telephone or mail” or request that a sample be destroyed if they provide information “to confirm that they have authority to make such a request.” The existence of these options, [the Biobank] argue[s], means that “there is a remedy available outside of litigation to prevent th[e] speculative harm [of misuse or discrimination] from occurring.” (Appellee Biobank Br. 9.) However, Defendants cite no cases explaining what the significance of alternate remedies being available has in standing analysis, and Plaintiffs correctly point out that this argument suggests there is an exhaustion-of-remedies requirement to § 1983 claims, which Supreme Court precedent has expressly rejected. See *Monroe v. Pape*, 365 U.S. 167, 183, 81 S.Ct. 473, 5 L.Ed.2d 492 (1961) (“The federal remedy [under § 1983] is supplementary to [any] state remed[ies], and the latter need not be first sought and refused before the federal one is invoked.”).

⁶ Despite his counsel arguing to use this process, Dr. Yancey himself testified he does not know about any “postextraction request system... that allows parents to ask for samples to be destroyed after they’ve gotten into the Biobank.” **Yancey Dep., ECF No. 135-40, PageID.2397 (p. 46)**.

Kanuszewski, 927 F.3d at 409 fn.5. The Sixth Circuit is right. See *Patsy v. Fla. Bd. of Regents*, 457 U.S. 496, 507 (1982). There is no requirement for Plaintiffs to use a self-created administrative process, which Dr. Yancey prefers, to fix his contribution to the unconstitutional scheme in lieu of relief under Section 1983.

B. Dr. Yancey is involved and liable.

After pages and pages of teeing up the background on this case and broadly discussing newborn screening, Dr. Yancey broadly asserts that “Dr. Yancey has not taken any action to violate the rights of Plaintiffs.” **ECF No. 149-1, PageID.4879.** Such simplicity-in-conclusion fails to acknowledge Dr. Yancey’s role in this unconstitutional process. He can be enjoined for his particular part of the whole. See *McNeil v. Comm. Probation Servs., LLC*, 945 F.3d 991, 996 (6th Cir. 2019). This case has two primary constitutional theories asserted—a violation of substantive due process and violation of the Fourth Amendment. While consent would provide a defense to both, Dr. Yancey never argues that consent was provided to or secured by him (as to the Biobank)—largely because the record is fully devoid of any consent secured for the Biobank. **Yancey Dep., ECF No. 135-40, PageID.2397 (p. 46).**

Fourth Amendment

The Fourth Amendment protects privacy. *Cardwell v. Lewis*, 417 U.S. 583, 589 (1974). For this claim, the Sixth Circuit has provided the law of the case.⁷ First, the Sixth Circuit noted that “this claim is analytically distinct from... whether drawing the children’s blood and screening it for diseases violated the children’s Fourth Amendment right.” *Kanuszewski*, 927 F.3d at 424. “If drawing and screening the blood was unconstitutional, it is still possible that the ongoing retention, storage, or use of the sample constitutes a separate, independent violation.” *Id.* “And if drawing and screening the blood was constitutional, it may still have become an illegal seizure if Plaintiffs suffered a further, unlawful, deprivation of their interests at some later point.” *Id.* “If [it] is indeed Defendants’ purpose in retaining the children’s blood samples [to conduct research on children’s stored blood samples and seek to derive profit from the children’s samples by selling them to third parties], then their ongoing, indefinite seizure of the samples is unreasonable.” *Id.* Unreasonableness means unconstitutionality.

⁷ “Upon remand of a case for further proceedings after a decision by the appellate court, the trial court must proceed in accordance with the mandate and the law of the case as established on appeal... implement[ing] both the letter and the spirit of the mandate, taking into account the appellate court’s opinion and the circumstances it embraces.” *United States v. Moored*, 38 F.3d 1419, 1421 (6th Cir. 1994). The goal of the doctrine is to “enforce a district court’s adherence to an appellate court’s judgment.” *Miller v. Maddox*, 866 F.3d 386, 390 (6th Cir. 2017).

That is exactly what is happening. Dr. Yancey is part of a scheme which indefinite stores the infants' blood samples for third parties to conduct research on the children's stored blood spots, **Specimen Policy, ECF No. 135-22, PageID.2226 (§D)**, and to derive profit from the same. See **Yancey Dep., ECF No. 135-40, PageID.2397-2398 (pp. 49-50)** ("we do have our own price list... They charge, and then we charge also."); **BioTrust Business Plan, ECF No. 135-7, PageID.2107** (using infant blood samples for a "significant revenue stream of several million dollars"). As such, Dr. Yancey is committing a Fourth Amendment violation as provide by *Kanuszewski*. Plaintiffs further agree "[i]t does not seem that the health of the child justifies the state [or Dr. Yancey] in taking any actions with respect to the blood samples after it has finished screening the samples for diseases." *Kanuszewski*, 927 F.3d at 424.⁸

Substantive Due Process

As for substantive due process, the Sixth Circuit held that the question is "whether Defendants' subsequent retention, transfer, and storage of the

⁸ The Fourth Amendment's right to be "secure in their persons" from government intrusion includes medical testing upon and the extraction of deeply-private medical and genetic information/data from our children absent consent. *Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1214 (10th Cir. 2003).

samples violate the parents' fundamental rights." *Kanuszewski*, 927 F.3d at 420. It went on to hold—

Plaintiffs allege that after screening children's blood samples for diseases, Defendants retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties. Plaintiffs allege that these actions are undertaken without informed parental consent. [Assuming these [above] allegations are true], Defendants' actions constitute a denial of the parents' fundamental right to direct the medical care of their children, and their actions must survive strict scrutiny.

Id. On remand, Plaintiffs have easily proven (and Dr. Yancey has conceded) what was previously alleged—Dr. Yancey is in joint-concert with other state actors who have caused the retention of blood samples, transferred them to the Biobank, and Dr. Yancey stores them indefinitely for further use by the state or third parties. **ECF No. 135.** As the Sixth Circuit already found, such “constitute[s] a denial of the parents' fundamental right to direct the medical care of their children.” *Id.* And, this is the law of the case. *Moored*, 38 F.3d at 1421. In order to survive this constitutional infirmity, Dr. Yancey needs to prove his actions pass strict scrutiny. By his briefing, he never even tries.⁹

⁹ In his briefing, Dr. Yancey argues “the blood draws taken from newborns to screen for congenital disease or disorder are very clearly done to preserve the public health, and are squarely within the authority of the legislature,” suggesting such is a compelling governmental interest. But this case is not about the screening portion of NBS testing but the post-screening activities, i.e. the retention, transfer, and storage of the blood samples. Dr. Yancey never argues or asserts there is a compelling government interest regarding the latter. **ECF No. 149-1, PageID.4885-4886.** His focus is misplaced. He then goes on to argue that there is narrow tailoring because “Michigan newborn infant screening program is a law of neutral applicability, effecting all babies born in Michigan,

He fails his burden.

C. Plaintiffs have suffered or are threatened to suffer injury.

Dr. Yancey lastly argues that because these particular infants' blood spots are still in storage—without consent—but have not yet been used by third-party researchers to extract deeply private medical and genetic information and to further obtain physiological data, no harm was suffered. As such, according to Dr. Yancey, the constitutional violation has technically not yet occurred. This argument is both meritless and has been rejected.

It is Plaintiffs' position that a cognizable injury is occurring now. The injury is the interference with the infants' personal autonomy and the invasion and evisceration of their personal and medical privacy via the unauthorized retention of their blood samples containing extractable or already extracted deeply private medical and genetic information without sufficient informed parental consent. That is concrete, current, and ongoing harm.

designed to promote the public health and welfare through a minimally invasive process.” **ECF No. 149-1, PageID.4887**. Again, the focus is wrong—he does not argue or provide proof that his portion of the retention, transfer, and storage of the blood samples (as oppose to the screening) is narrowly tailored. He simply fails to meet his governmental burden. E.g. *Cole v. City of Memphis*, 97 F. Supp. 3d 947, 961 (W.D. Tenn., 2015); see also *Johnson v. City of Cincinnati*, 310 F.3d 484, 504 (6th Cir. 2002) (“In considering whether a government regulation is narrowly tailored, it is not enough that the regulation achieves its ostensible purpose, it must do so without unnecessarily infringing upon constitutionally protected rights.”). One simple and more narrowly-tailored process (of many possibles) would be to obtain sufficient prior informed parental consent before transferring the blood spots from the State Defendants to the Biobank.

However, even if the Court believes otherwise and treats it only as threatened to become harmed, it is still actionable. Common sense and US Supreme Court precedent confirms that one need not wait until the ax fully falls before a remedy can be sought. *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014); see also *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128-129 (“[W]here threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat”).

A Ninth Circuit case, *In re Zappos. com, Inc.*, 888 F.3d 1020 (9th Cir. 2018), is instructive. In *Zappos*, hackers breached the servers of an online retailer and stole (i.e. had no consent to take) millions of customers’ names, account numbers, passwords, email addresses, billing and shipping addresses, telephone numbers, and credit and debit card information. Some had their identities used by criminals; many had not (yet). Several customers filed putative class actions asserting that the online retailer had not adequately protected the customers’ personal information it held. The retailer argued—along the same lines tried by Dr. Yancey—that no harm has occurred unless and until the particular customer’s already stolen identity was first used improperly. The Ninth Circuit rejected the argument. It

reconfirmed that an allegation of future injury can suffice if there is a “substantial risk” that the harm will occur. *Id.* at 1026.

The privacy-invaded infants here are in the same status as the privacy-invaded customer victims in *Zappos*. An entity (here the Biobank) has taken possession and control of their blood spots, which contain deeply private medical and genetic information which can be shared with third parties at any time without any prior obtained consent. Once distributed without consent, there is a fulfilled invasion of privacy and unfixable interference with their personal autonomy. Like the stolen identifies, harm can occur at any moment at the whim of another. At the direction of someone other than the parents, the infants’ blood spots can be searched without consent. **Yancey Dep., ECF No. 135-40, PageID.2395-2396 (pp. 40, 42-45).** Dr. Yancey confirms he currently possesses the infants’ blood samples and consent is never sought when a sample is selected and pulled for use by third parties. There is clear “substantial risk” of threatened harm by the government and Dr. Yancey providing access and utilization by third parties without sufficient past or future consent.

CONCLUSION

Dr. Yancey is one part of a multi-official scheme which destroys the infants’ rights of medical privacy and directly interferes with the personal

autonomy to make key decisions about deeply private medical and genetic information and other physiological data. He is not entitled to summary judgment.

RELIEF REQUESTED

Based upon the foregoing, the Court is requested to deny summary judgment in favor of Dr. Yancey and instead grant summary judgment against him in favor of Plaintiffs.

Date: April 26, 2021

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison
OUTSIDE LEGAL COUNSEL PLC
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Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I, the undersigned attorney of record, hereby certify that on the date stated below, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel or parties of record.

Date: April 26, 2021

RESPECTFULLY SUBMITTED:

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